UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC.,

Plaintiffs and Counter-Defendants,

-against-

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, AVADEL SPECIALTY PHARMACEUTICALS, LLC,

Defendants and Counterclaimants.

x

No. 17 Civ. 9922 (CM)

MEMORANDUM DECISION AND ORDER GRANTING DEFENDANTS' MOTIONS FOR JUDGMENT ON THE PLEADINGS AND SETTING A TRIAL SCHEDULE

McMahon, C.J.:

These motions arise in the context of a 17-year-old battle between the parties over the development of competing drugs to treat nocturia due to nocturnal polyuria, a disease of the kidneys that causes excessive nighttime urination.

In 2012, Ferring Pharmaceuticals Inc., Ferring B.V. and Ferring International Center S.A. ("collectively, "Ferring")—the same three plaintiffs in the present lawsuit—sued Dr. Seymour Fein, a former Ferring consultant, along with two entities he formed, Serenity Pharmaceuticals, LLC ("Serenity") and Reprise Biopharmaceutics LLC ("Reprise"). *See Ferring B.V. et al. v. Allergan, Inc. et al*, No. 12 Civ. 2650 (S.D.N.Y.) (hereinafter referred to as the "2012 Action"). Among other things, Ferring alleged that Dr. Fein "did not invent any subject matter" covered by two patents for which he applied and obtained patent protection—U.S. Patent No. 7,405,203 (the

"'203 Patent") and U.S. Patent No. 7,579,321 (the "'321 Patent")—and therefore sought to "correct the inventorship" of those two patents, pursuant to 35 U.S.C. § 256, to replace Dr. Fein with Ferring scientists. (12 Civ. 2650 Dkt. No. 73 ¶¶ 112, 127.) On August 31, 2015, the Hon. Robert W. Sweet granted summary judgment dismissing Ferring's correction of inventorship claims. He concluded that Ferring was equitably estopped from challenging Dr. Fein's status as the inventor of the '203 and '321 Patents, because it unduly "delayed advancing [its] claims in this litigation in order to impose the risks and costs of drug development on [Dr. Fein and his co-defendants] and then to obtain patent correction in [its] favor[.]" (12. Civ. 2650, Dkt. No. 190 at 2 (hereinafter referred to as the "Equitable Estoppel Opinion" or "Opinion").)[1] The 2012 Action, which includes claims directed at other patents that Dr. Fein obtained, is ongoing.

In 2017, Ferring brought this action against Defendants Serenity, Reprise, and—later—Avadel Specialty Pharmaceuticals, LLC ("Avadel"), which is the exclusive sublicensee of the'203 and '321 Patents.[2] Among other things, Ferring seeks two declarations: *first*, that the '203 and '321 Patents suits are unenforceable, because Dr. Fein engaged in "inequitable conduct" before the United States Patent and Trademark Office ("PTO") by representing himself as the sole inventor of those patents (*see* Ferring's First Amended Compl. ("Am. Compl."), dated June 30, 2017, ¶¶ 138–48, Dkt. No. 18); and *second*, that the '203 and '321 Patents are invalid, pursuant to 35 U.S.C. § 102, in part because Dr. Fein "did not himself invent the subject matter claimed" in those patents (*id.* ¶ 116).

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[1] The Equitable Estoppel Opinion is also appended as Exhibit A to Defendant Avadel's Answer. (*See* Dkt. No. 143-1).

[2] Ferring's initial complaint also asserted claims against Allergan, Inc., which is also a defendant in the 2012 Action. However, Ferring voluntarily dismissed all claims against Allergan in this case on August 1, 2017. (*See* Dkt. No. 35.)

Defendants now bring two motions for judgment on the pleadings, pursuant to Fed. R. Civ. P. 12(c), in which they ask the Court to dismiss Ferring's inequitable conduct claim (Count V) as well as Ferring's allegation, offered in support of its patent invalidity claim (Count I), that Dr. Fein did not invent the '203 and '321 Patents.

The question presented by Defendants' motion is whether Ferring is foreclosed from asserting those claims in light of the findings of fact and conclusions of law that are contained in the Equitable Estoppel Opinion.

The answer to this question is yes. Defendants' motions are granted.

I. Factual Background and Prior Proceedings

a. Patents in Suit

This action—unlike the 2012 Action—solely concerns the '203 and '321 Patents.[3]

On July 29, 2008, the PTO issued the '203 Patent, which is titled "Pharmaceutical Compositions Including Low Dosages of Desmopressin." (Am. Compl. Ex. C.) It lists Dr. Seymour Fein as the sole inventor. (*Id.*) Reprise is the lawful owner of all right, title, and interest in the '203 Patent. (*Id.* ¶ 15.) Serenity is an exclusive licensee of the '203 Patent, with the right to enforce it. (*Id.* ¶ 16.) Avadel is an exclusive sublicensee of the '203 Patent, with the right to enforce it. (Ferring's Answer and Countercl. ("Ferring's Counter."), dated July 19, 2018, ¶ 8, Dkt. No. 115.)

On August 25, 2009, the PTO issued the '321 patent, which also is titled "Pharmaceuticals Compositions Including Low Dosages of Desmoproessin." (Am. Compl. Ex. D.) Again, Dr. Fein is the sole inventor. (*Id.*) The same ownership arrangement that applies to the '203 Patent applies to the '321 Patent as well: Reprise is the lawful owner of all right, title,

[3] Ferring also brought claims related to U.S. Patent No. 7,799,761 (the "'761 Patent"). However, all claims relating to the '761 Patent were dismissed on May 13, 2019. (*See* Dkt. No. 495.)

and interest in the '321 Patent. (*Id.* ¶ 8.) Serenity is an exclusive licensee of the '321 Patent, with the right to enforce it. (*Id.* ¶ 16.) And Avadel is an exclusive sublicensee of the '321 patent, with the right to enforce it. (Ferring's Countercl. ¶ 8.)

b. The Parties

Desmopressin is a synthetic hormone that is used to treat a variety of disorders related to excessive urine production, including nocturia. (Am. Compl. ¶ 75.) While effective, it also poses a risk of having reduced sodium levels in the blood, a condition also known as hyponatremia. (*Id.* ¶ 76.)

Ferring is an innovator in the field of desmopressin. (*Id.* ¶¶ 4, 75.) In 1972, Ferring developed the world's first industrial scale pharmaceutical desmopressin products by launching desmopressin as a treatment for central diabetes insipidus. (*Id.* ¶ 80.) It continues to conduct research and development on desmopressin to this day. (*Id.*)

Dr. Fein, a board-certified internist and medical oncologist, is—as noted—the named inventor of the '203 and '321 Patents. (*Id.* ¶ 14; Countercl. ¶ 26.) Dr. Fein and his other business partners formed Serenity, Reprise, and Avadel to commercialize his alleged inventions. (Am. Compl. ¶ 14.)

c. Dr. Fein's Consulting Work for Ferring

In the late 1990s, Ferring sought to develop an "orodispersible" (meaning orally disintegrating) desmopressin tablet. (*Id.* ¶ 83.)

During that period, Dr. Fein worked as a consultant for Ferring. (*See generally* Equitable Estoppel Opinion ¶¶ 30–51.) Among other things, he was responsible for assisting in the research and development of desmopressin-related products. (*Id.*)

Dr. Fein alleges that he discovered that desmopressin could be effective in much lower doses than previously known, which would also reduce the risk of hyponatremia. (Countercl. ¶¶

26–27.) He purportedly communicated this discovery to Ferring to help it design clinical studies to test his ideas. (*Id.*) He further alleges that he "suggested" to Ferring that desmopressin could be delivered "sublingually," *i.e.*, absorbed under the tongue by way of a dissolvable tablet, and that this particular method would improve "bioavailability and allow for a greater percentage of desmopressin in the formulation to reach the bloodstream." (*Id.* ¶ 27.)

On May 7, 2002, Ferring filed a patent application in Great Britain, Patent Application No. 0210397.6 ("GB '397"), for an orodispersible desmopressin formulation. (Am. Compl. ¶ 57.) GB '397 disclosed a dosage form of desmopressin adapted for sublingual absorption. (Equitable Estoppel Opinion ¶¶ 1–2). There was no requirement that this early priority document identify or name any inventors, and so none was listed. (*Id.* ¶ 3; *accord* Am. Compl. ¶ 57.).

On September 20, 2002, Ferring filed a Patent Cooperation Treaty ("PCT") application, PCT/1B02/04036 ("PCT '036"), claiming priority to GB '397. (Am. Compl. ¶ 58.) PCT '036 listed Dr. Fein among the inventors of the patent. (Equitable Estoppel Opinion ¶¶ 4–5.)

d. Dr. Fein's Termination and Efforts to Secure Intellectual Property Protection

On November 7, 2002, Ferring formally terminated Dr. Fein's consulting agreement after he declined to retroactively assign his inventions to Ferring. (*Id.* ¶ 29.) Dr. Fein then proceeded to take certain steps to assert his purported intellectual property rights in the subject matter claimed by Ferring's patent applications. Specifically, over the ensuing six months, Fein's attorney, William Speranza, engaged in a back-and-forth correspondence with Ferring through its counsel, Patricia Barclay. (*See generally* Equitable Estoppel Opinion; *see also* Dkt. No. 143

Ex. B (Speranza-Barclay correspondence).) That correspondence, which served as the factual basis for Judge Sweet's Equitable Estoppel Opinion, is detailed below.[4]

On November 21, 2002, Speranza sent a letter to Ferring on Dr. Fein's behalf, stating that Dr. Fein considered himself the inventor of a "'sublingual, transmucosal route of delivery which affords a number of advantages . . . including enabling the effective use of formulations having reduced concentrations of desmopressin.'" (*Id.* ¶¶ 30–31.) Speranza further asserted that Dr. Fein had not assigned any inventorship rights to Ferring during his consultancy and therefore retained ownership rights in any patents that might develop from Ferring's patent applications. (*Id.* ¶ 32.)

On January 30, 2003, Speranza sent a second letter to Ferring, reiterating that Dr. Fein "'possessed ownership rights in the invention, the pending application therefor and any patents that may issue on his invention.'" (*Id.* ¶¶ 34–35.) He also stated that Dr. Fein was considering whether he would "'take steps independent of Ferring'" to protect his patent rights if Ferring did not acknowledge Fein's interests in Ferring's existing patent applications and promise not to take any actions that "'would in any manner affect, limit, or compromise [Fein's] inventorship rights and ownership interests.'" (*Id.* ¶ 36.)

Barclay responded to Mr. Speranza's letter on April 9, 2003. She advised that Ferring decided to drop the feature "adapted for sublingual administration" from PCT '036 because sublingual administration "'does not in this context confer a delimitation *i.e.*[,] novelty.'" (*Id.* ¶¶ 37–38.) Consequently, she stated, Ferring planned to remove Dr. Fein as an inventor from PCT '036. (*Id.* ¶ 39.)

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[4] Unless otherwise noted, the Court will cite the Equitable Estoppel Opinion for exact excerpts from the Speranza-Barclay correspondence so as to reflect that these exchanges were directly considered by Judge Sweet in his Opinion.

On April 17, 2003, Speranza sent an email in response. He acknowledged that Dr. Fein did not object to Ferring's decision to drop Dr. Fein as an inventor from PCT '036. (*Id.* ¶¶ 40–41.) He also clarified that Dr. Fein believed that he had invented a "'sublingual, transmucosal route of delivery which affords a number of advantages in the efficacy and safety of desmopressin administration, including enabling the effective use of formulations having reduced concentrations of desmopressin.'" (*Id.* ¶ 42.) Accordingly, he stated, "'Dr. Fein is planning to proceed with pursuing patent protection covering the sub-lingual administration route and the associated low dosage possibilities enabled by same which he invented, all at his own expense going forward and with the understanding that Ferring relinquishes any ownership claims thereto.'" (*Id.* ¶ 43.) "He plans to claim priority to the same UK application [GB '397], as is of course proper. In order to do this, however, we need the particulars of the UK filings, namely the application number and confirmation of the 7 May 2002 filing date thereof." (Dkt. No. 142 at AGN_FER000002769.)

On April 29, 2003, Barclay acknowledged receipt of Speranza's earlier letter and advised that Ferring believed that Dr. Fein's purported invention was "'already in the public domain[,]'" and thus was not subject to patent protection. (Equitable Estoppel Opinion ¶¶ 44–46.) She added, "'I cannot of course say now that Ferring will not make any claim as to ownership of any other material Dr. Fein may include in any patent application as without seeing the text and knowing what claims for novelty or inventive steps he has in mind[;] I cannot be sure that this does not cover matters to which employees of the Ferring Group have contributed or regarding which Dr. Fein is bound to us by terms of confidentiality.'" (*Id.* ¶ 46.) Consequently, she stated that Ferring would not pursue any claims directed at "'the low dosage possibilities enabled by the sublingual administration route.'" (*Id.* ¶ 47.) She did, however, provide Speranza with the

date and application number for GB '397, ensuring him that this information would suffice to enable Dr. Fein to claim priority. (Dkt. No. 143 Ex. B. at AGN_FER000002772 ("I believe this is sufficient to claim priority.").)

e. Dr. Fein's Patent Applications

On May 7, 2003—approximately one week after Barclay's latest correspondence—Dr. Fein filed PCT Patent Application No. PCT/US03/14463, claiming priority to GB '397. (Am. Compl. ¶ 60.)

On November 12, 2003, Dr. Fein filed continuation-in-part U.S. Patent Application 10/706,100, based off his PCT Patent Application No. PCT/US03/14463. (*Id.* ¶ 15; Equitable Estoppel Opinion ¶ 11.)

On December 9, 2004—nearly eighteen months removed from the parties' earlier communication—Barclay sent a letter to Speranza expressing her "'tru[e] surprise[] . . . that Dr. Fein had proceeded with [his PCT] application to which we believe he has no entitlement and which in particular discloses information confidential and proprietary to Ferring to which Dr. Fein had confidential access during his engagement as [a] consultant.'" (Equitable Estoppel Opinion ¶ 50.) She added, "'Ferring will take all necessary steps to protect its rights and interests,'" and concluded by warning Dr. Fein that Ferring would "'commence formal action'" if it "'did not receive a full and satisfactory explanation within 14 days[.]'" (*Id.* ¶ 52.)

Mr. Speranza sent two letters in response. (*Id.* ¶ 53.)

In the first, he referred Barclay to the parties' "'dealings and communications throughout 2003'" with Ferring that "'made clear that Ferring made no claim to low dosage desmopressin as its invention.'" (*Id.* ¶ 55.) He also reminded Barclay that his April 17, 2003 email specifically informed her that "'Fein is planning to proceed with pursuing patent protection covering the sub-

lingual administration route and the associated low dosage possibilities enabled by same.'" (*Id.* ¶ 54.) He concluded, "'We trust this response will put this matter to rest.'" (*Id.* ¶ 56.)

In his second letter—which he sent later that same day—Speranza sent Barclay a copy of Dr. Fein's continuation-in-part U.S. patent application. (*Id.* ¶ 57.)

Following this final exchange of correspondence between Ferring and Dr. Fein's counsel, Ferring took no direction action in connection with Dr. Fein's patent applications (and later patents) for over seven years. (*Id.* ¶ 58.)

f. Dr. Fein's Attempt to Commercialize His Inventions

"On the basis of his communications with Ferring, Dr. Fein inferred that he was free to independently pursue patent protection for his invention without interference." (*Id.* ¶ 59.)

Over the ensuing seven-year period, Dr. Fein invested substantial resources in independently developing his desmopressin treatment method. Among other things, he sponsored and conducted various clinical studies; filed an Investigational New Drug ("IND") application with the Food and Drug Administration (the "FDA"); met with the FDA regarding his IND application; and formed Serenity and Reprise for the purpose of commercially developing his invention and protecting his intellectual property rights. (*Id.* ¶¶ 59–83.) In so doing, he provided the Speranza-Barclay correspondence to his business partners to assist in their due diligence, and they, in turn, relied on that correspondence in doing business with him. (*Id.* ¶¶ 65–66, 75, 78.)

As noted earlier, during the period in which Dr. Fein sought to commercialize his inventions, Dr. Fein's patents issued in the United States—specifically, the '203 and '321 Patents issued in the summers of 2008 and 2009, respectively. *Supra* at 3.

When all was said and done, from 2003 to 2012, Dr. Fein and his business partners invested over $60 million dollars in, among other things, design, clinical research, and

manufacturing, all in order to develop a desmopressin product protected by Dr. Fein's patents. (*Id.* ¶ 84.)

g. The 2012 Action

On April 4, 2012, Ferring brought suit in this District, naming Dr. Fein, Serenity, and Reprise, among others, as defendants. (12 Civ. 2650 Dkt. No. 1.) It claimed, *inter alia*, that two Ferring employees made "significant inventive contributions" to the '203 and '321 Patents (12 Civ. 2650 Dkt. No. 73 (First Amended Complaint) ¶ 95), and that Dr. Fein, in turn, "did not invent any subject matter covered" by those two patents (*id.* ¶ 112 ('203 Patent), ¶ 127 ('321 Patent).) Therefore, Ferring sought to replace Dr. Fein as the named inventor of those patents, pursuant to 35 U.S.C. § 256.

On April 17, 2015, the defendants in the 2012 Action moved for summary judgment on Ferring's inventorship claims. (12 Civ. 2650 Dkt. No. 132.) They argued that Ferring was equitably estopped to assert those claims, because it sat on the sidelines for seven years while Dr. Fein, relying upon the Speranza-Barclay correspondence (and Ferring's silence thereafter), invested millions in developing his desmopressin products.

Judge Sweet agreed. He concluded that Ferring's conduct in corresponding with Speranza was "misleading;" its efforts to replace Dr. Fein as the named inventor of the '203 and '321 Patents "contradict[ed] [the] earlier position" that Barclay conveyed to Dr. Fein—that Ferring would not pursue claims against Dr. Fein challenging his purported inventions. (*See* Equitable Estoppel Opinion at 27; *see also* 22–28.) Judge Sweet further determined that the defendants "relied upon Ferring's inaction by spending several years commercializing [Dr. Fein's invention]," including by forming Reprise and Serenity (*id.* at 29), and that Ferring's misleading conduct, which caused the defendants millions to invest tens of millions of dollars in developing Dr. Fein's product, amounted to prejudice (*id.* at 34). Accordingly, he ruled that

Ferring was equitably estopped from seeking to "correct" the inventorship shown on the '203 and '321 Patents.

The 2012 Action is ongoing. A bench trial (once begun but interrupted, for reasons having nothing to do with this decision) is scheduled for July 24, 2019, before the Hon. P. Kevin Castel. (12 Civ. 2650 Dkt. No. 372.)

h. Present Case

On April 28, 2017, Ferring filed the present action against Serenity, Reprise, and Allergan, Inc.[5] in the District of Delaware, seeking a declaration that the '203 and '321 Patents are invalid and unenforceable on various grounds.

Serenity and Reprise moved to transfer the case to the Southern District of New York, arguing that the case was "related" to the 2012 Action. (*See* D. Del. 17 Civ. 479 Dkt. Nos. 11–12.) The Delaware court granted the motion to transfer. (D. Del. 17 Civ. 479 Dkt. No. 58). However, the Court's Assignment Committee ruled that the cases were not "related" in the technical sense of our Court rules, in that they concerned different patents. The 2017 case was initially assigned to Judge Hellerstein. The case ended up before Judge Sweet, pursuant to Rule 14 of the Southern District of New York's Rules for the Division of Business Among Judges, after Ferring vigorously argued that it should not be sent to Judge Sweet despite his superior knowledge of the Fein-Ferring dispute. *See supra* at 4–10. The case was transferred to me after Judge Sweet died in mid-March this year.

II. Discussion

Defendants now bring two motions for judgment on the pleadings under Fed. R. Civ. P. 12(c). Both motions arise out of Judge Sweet's Equitable Estoppel Opinion.

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[5] Ferring subsequently dismissed all claims against Allergan. (*See* Dkt. No. 35.)

First, Defendants argue that Ferring's claim of inequitable conduct (Count V) must be dismissed, because Judge Sweet already determined, in the course of granting Defendants' motion for summary judgment on equitable estoppel grounds, that Dr. Fein reasonably believed that Ferring did not dispute his ownership. It follows, they argue, that a trier of fact could not reasonably infer that Dr. Fein either knowingly or intentionally misled the PTO, which is an element of the inequitable conduct claim. (Am. Compl. ¶¶ 138–48.)

Second, Defendants argue that Ferring should be collaterally estopped from claiming that Dr. Fein is not the inventor of the '203 and '321 Patents—an assertion that Ferring presses in support of its claim that the Patents in Suit are invalid under 35 U.S.C. § 102 (Count I). (*See* Am. Compl. ¶ 116.) According to Defendants, Ferring cannot re-challenge Dr. Fein's inventorship of the '203 and '321 Patents, because that issue was necessarily resolved when Judge Sweet disposed of Ferring's earlier claims for a correction of inventorship under 35 U.S.C. § 256.

Dismissal under Rule 12(c) is "appropriate where material facts are undisputed and where a judgment on the merits is possible merely by considering the contents of the pleadings." *Sellers v. M.C. Floor Crafters, Inc.*, 842 F.2d 639, 642 (2d Cir. 1988). The standard for assessing a Rule 12(c) motion for judgment on the pleadings is identical to that of a Rule 12(b)(6) motion to dismiss the complaint for failure to state a claim upon which relief can be granted. *Ziemba v. Wezner*, 366 F.3d 161, 163 (2d Cir. 2004) (citations omitted). To survive a motion to dismiss, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp v. Twombly*, 550 U.S. 544, 570 (2007). A well-pleaded complaint requires "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

"On a 12(c) motion, the court considers 'the complaint, the answer, any written documents attached to them, and any matter of which the court can take judicial notice for the factual background of the case.'" *L-7 Designs, Inc. v. Old Navy,* LLC, 647 F.3d 419, 422 (2d Cir. 2011) (quoting Roberts *v. Babkiewicz*, 582 F.3d 418, 419 (2d Cir. 2009)). Accordingly, the Court can consider Defendants' Answer and Counterclaims as well as take judicial notice of Judge Sweet's findings in the 2012 Action, including those contained in the Equitable Estoppel Opinion. The Court can also consider the direct text of all patent applications, including those not appended as exhibits, because those are both incorporated by reference and integral to the Amended Complaint. *See DiFolco v. MSNBC Cable LLC*, 622 F.3d 104, 111 (2d Cir. 2010).

a. Defendants' Motion for Judgment on the Pleadings to Dismiss Count V is Granted

Ferring seeks a declaratory judgment of unenforceability of the Patents in Suit due to alleged inequitable conduct committed during their prosecution.

"[W]hether inequitable conduct has been adequately pleaded is a question of Federal Circuit law because it pertains to or is unique to patent law." *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) (internal quotation marks and citation omitted).

A claim for inequitable conduct is subject to Rule 9(b)'s exacting pleading standard. *Id.* at 1328–29. "To plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at 1328. Although knowledge and intent may be averred generally, pleadings of inequitable conduct under Rule 9(b) must include "sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the material information or of the falsity of

the material misrepresentation; and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1328–29. "A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith." *Id.* at 1329 n.5 (internal citation omitted). Activities that seem "'inconsistent with knowledge of illegality or fear of a lawsuit'" do not support an inference of fraudulent intent, even at this preliminary stage. *Id.* (quoting *Greenstone v. Cambex Corp.*, 975 F.2d 22, 26 (1st Cir. 1992) (Breyer, C.J.)).

Ferring alleges that Dr. Fein knew and intentionally withheld from the PTO that (*i*) he was not the inventor of the subject matter claimed in the patents in suit; (*ii*) that his claim of priority to GB '397 was false; and (*iii*) that there was a dispute with Ferring over "Example 8" from the Patents in Suit. (Am. Compl. ¶¶ 140–48.)

1. Inventorship of the Patents in Suit

To support its first allegation of inequitable conduct, Ferring points to a "Combined Declaration and Power of Attorney for Sole Inventor" (hereinafter referred to as the "Combined Declaration"), dated March 14, 2004, that Dr. Fein submitted to the PTO in support of his patent applications. (Am. Compl. ¶¶ 141–43; *see also id.* Exs. Q, R (Combined Declaration submitted in support of 203 and '321 Patents, respectively).) The Combined Declaration, which Fein re-submitted on July 26, 2007 and July 15, 2008 during prosecution of the '203 and '321 Patents, respectively, states that Dr. Fein is the sole inventor of the Patents in Suit. (Am. Compl. ¶¶ 141–42.) According to Ferring, Dr. Fein had a duty to disclose material information related to patentability, including information about inventorship conflicts. (*Id.* ¶¶ 141, 146–48 (citing Manual Patent Examining Procedure § 2001.04 & 37 C.F.R. §1.56).) Dr. Fein's failure to make that disclosure and representation that he solely invented the '203 and '321 Patents, Ferring avers, was misleading.

But Judge Sweet expressly determined the opposite. He found that Dr. Fein reasonably believed that he was sole owner of the Patents in Suit as a result of the Speranza-Barclay correspondence, and therefore was *not* aware of an inventorship conflict.

The only time that Ferring expressed concern with Dr. Fein's pursuing patent protection for his inventions was on December 9, 2004. (*See* Equitable Estoppel Opinion ¶¶ 50–52.) It was then that Barclay alerted Speranza that she believed that Dr. Fein's PCT application US2003/014463 "'contain[s] an invention to which we believe he has no entitlement[,] and which in particular discloses information confidential and proprietary to Ferring to which Dr. Fein had confidential access during his engagement as consultant.'" (*Id.* ¶ 51.) Just days later, Speranza responded to that claim, reminding Barclay that his earlier email, dated April 17, 2003, had apprised her (and Ferring) that, "'Fein is planning to himself proceed with pursuing patent protection covering the sub-lingual administration route and the associated low dosage possibilities enabled by the same.'" (*Id.* ¶ 54.) The parties' "'dealings and communications throughout 2003'" made "'clear that Ferring had no claim to low dosage desmopressin as its invention.'" (*Id.* ¶ 55.) Speranza concluded his letter by saying, "'We trust this response will put this matter to rest.'" (*Id.* ¶ 56.) He then sent a follow-up letter referencing and attaching "for [Barclay's] convenience" Dr. Fein's continuation-in-part U.S. patent application in the "interests of completeness." (Dkt. No. 143 Ex. B at AGN_FER000002786.)

Following this exchange of correspondence between Speranza and Ferring, "Ferring took no direct action on Dr. Fein's patent applications, and later patents, for over seven years." (Equitable Estoppel Opinion ¶ 58.)

Judge Sweet reached a number of conclusions on the basis of these undisputed facts. First, he found, as a matter of fact, that Dr. Fein "inferred" "that he was free to independently

pursue patent protection for his invention without interference[]" from Ferring's silence after Speranza sent his last message. (*Id.* ¶¶ 58–59.) Second, he determined, "Until Ferring began asserting its inventorship claims, none of the Defendants [including Dr. Fein] had reason to believe Ferring would dispute inventorship of the low-dosage inventions." (*Id.* at 30.) Third, he concluded, "Defendants . . . reasonably rel[ied] on Ferring's acquiescence to Dr. Fein pursuing his own patents[.]" (*Id.* at 34.)

In short, Judge Sweet concluded, as a matter of undisputed fact, that Dr. Fein reasonably believed, in the face of Ferring's silence (and seeming acquiescence) in his application, that Ferring did not dispute his inventorship of the subject matter claimed in the Patents in Suit. In the face of Judge Sweet's finding, no trier of fact could possibly draw the inference that Ferring seeks—namely, that Dr. Fein had the specific intent to mislead the PTO about his being the sole inventor of the Patents in Suit. That inference is fundamentally incompatible with facts found by Judge Sweet, because "reasonable reliance" on Ferring's seemingly acquiescent conduct is incompatible with the scienter needed to sustain a claim of inequitable conduct.

According to Ferring, "At most Dr. Fein could have only reasonably believed that he invented 'sub-lingual administration' and the 'associated low dosage possibilities enabled by sub-lingual administration' of desmopressin"—not the full subject matter of the '203 and '321 Patents. (Ferring's Opp. to Def.'s First Mot. for J. on the Pleadings, dated Aug. 28, 2018, ("Ferring's First Opp."), at 10–11, Dkt. No. 168.) Ferring further argues that Judge Sweet's *Markman* decision, dated January 22, 2019 (Dkt. No. 421), supports this interpretation, because Judge Sweet's construction of the Patents in Suit—which he construed as not containing a "low dose" limitation—differs from the invention that Speranza and Barclay discussed in their correspondence—an invention, Ferring submits, that *was* "limited to low dose." (*See* Ferring's

Supp. Mem. of Law in Opp. to Defs.' Mots. J. on Pleadings, dated Feb. 5, 2019 ("Ferring's Supp. Mem."), at 6, Dkt. No. 456-1) (emphasis in original).)

Ferring's interpretation of the Equitable Estoppel Opinion is incorrect. In his Equitable Estoppel Opinion, Judge Sweet recognized that the inventions that were the subject of conversation between Barclay and Speranza included the inventive feature of establishing low plasma/serum levels of desmopressin. He stated:

> The low-dosage invention as described in the PCT at issue in the Speranza correspondence [PCT application US2003/014463] *is the same subject matter detailed in the patents-in-suit, down to the specific numerical quantity of desmopressin to be used.*"
> . . .
>
> Despite having threatened immediate legal action with respect to the patent application, Ferring did not disagree or otherwise challenge Mr. Speranza's assertion that low dosage development was Fein's intellectual property. Ferring was aware of two Fein patent applications that include claims for low desmopressin doses *and low desmopressin plasma concentration levels*. Ferring's December 9, 2004 letter reflects that the parties were discussing Dr. Fein's 2003 PCT application. Then, on December 14, 2004, Mr. Speranza sent Ms. Barclay Dr. Fein's first U.S. patent application. Both of those applications contained claims for specific low doses *and specific low plasma concentration levels*.

(Equitable Estoppel Opinion at 27–28 (emphases added).)

This passage illustrates that Judge Sweet specifically recognized that the inventions for which Dr. Fein sought patent protection in 2003 (*i.e.*, those embodied in PCT application US2003/014463 and U.S. patent application 10/706,100) included claims directed to low plasma concentrations without specific numerical dosage limitations. (U.S. Patent Application Publication No. 2004/0138098; International Publication No. WO2004/041153.) Moreover, these applications identified several routes of administration—not just sublingual—including intravenous infusion, subcutaneous, and transdermal. (*Id.*) Contrary to Ferring's contention, Judge Sweet did not conclude that Dr. Fein "reasonably rel[ied] on Ferring's acquiescence to Dr. Fein pursuing" patent protection *only* for the low dosage possibilities enabled by sublingual

administration of desmopressin; he concluded that Dr. Fein "reasonably re[lied] on Ferring's acquiescence to Dr. Fein pursuing *his own patents*[.]" (Equitable Estoppel Opinion at 34.)

On the basis of the Speranza-Barclay correspondence and Judge Sweet's interpretation thereof, the Court cannot infer that Dr. Fein fraudulently intended to mislead the PTO as to the inventorship of the '203 and '321 Patents.

2. Priority to GB '397

Ferring alleges that Dr. Fein knowingly misled the PTO in claiming priority to GB '397. According to Ferring, GB '397 embodied Ferring's work—not Fein's—and Fein had no right to claim priority to an application that he did not initially file, pursuant to 35 U.S.C. § 119. "Dr. Fein passed off Ferring's disclosures as his own work throughout the prosecution of the [P]atents in [S]uit, leading to the reasonable inference that Dr. Fein claimed priority to Ferring's work with an intent to deceive the PTO." (Ferring's First Opp. at 13; *see also* Am. Compl. ¶¶ 142–46.)

Viewed alongside the Speranza-Barclay correspondence and Judge Sweet's findings, this inference is also implausible.

Ferring's contention ignores the fact that Barclay—in response to an explicit request from Speranza explaining that Dr. Fein planned to file a patent application claiming priority to GB '397—provided Speranza with information about GB '397 in order to facilitate Dr. Fein's priority claim. The Equitable Estoppel Opinion incorporated a key exchange between Speranza and Barclay about Dr. Fein's intention to claim priority to GB '397. (*See* Equitable Estoppel Opinion ¶¶ 40–48.) On April 12, 2003, Speranza informed Barclay that:

> Dr. Fein is planning himself to proceed with pursuing patent protection covering the sub-lingual administration route and the associated low dosage possibilities enabled by the same which he invented, all at his own expense going forward and with the understanding that Ferring relinquishes any ownership claims thereto. He plans to claim priority to the same UK application [GB '397] as is of course proper. In order to do this,

> however, we need the particulars of the UK filing, namely, the application number and confirmation of the 7 May 2002 filing date thereof. At some point we will also need a certified copy of the UK application as filed. WOULD YOU PLEASE GET THIS INFORMATION TO ME JUST AS QUICKLY AS POSSIBLE, for otherwise there is risk of not being able to timely and properly claim priority to the UK application. . . . We will also need to formalize Ferring's relinquishment of any ownership rights in Dr. Fein's inventions, Dr. Fein's corresponding agreement as an inventor in your planned PCT application and relinquishment of any ownership rights in the subject matters you will be claiming, and the like. But in the meantime, the first order of business is for you to provide us with the requested information about the UK application.

(Dkt. No. 143 at AGN_FER000002769 (emphasis in original).)

Barclay responded twelve days later by conveying Ferring's belief that, "The low dosage possibilities enabled by the sublingual administration route are already available in the public domain. . . . This is the reason as we have explained that we will not be pursuing this claim." (*Id.* at AGN_FER000002772.) She then declined to give Speranza a copy of GB '397—but only because she did not believe Dr. Fein was entitled to review Ferring's own patentable subject matter "disclosed therein." (*Id.*) But, she concluded, "I can none the less [*sic*] advise that the initial filing was made in the UK on 7 May 2002 and was assigned number UK 02.10397.6. *I believe this is sufficient to claim priority*." (*Id.* (emphasis added).)

The rest, as they say, is history. Dr. Fein filed PCT application PCT/US03/14463 one week later, claiming priority over GB '397, and then filed a continuation in part U.S. patent application 10/706,100 based off that PCT application. Eighteen months later, Barclay expressed surprise, then Speranza promptly responded—and Ferring was not heard from again for seven years.

Judge Sweet interpreted this exchange to mean that Ferring, while believing that the low dosage administration of desmopressin was not patentable (because it was already in the public domain), nevertheless "acquiesce[d] to Dr. Fein pursuing his own patents." (*Id.* at 34.) The process of obtaining his own patents entailed claiming priority to GB '397—which Speranza

explicitly told Ferring he intended to do on April 12, 2003. Judge Sweet recognized this fact, writing, "Ferring did not disagree or otherwise challenge Mr. Speranza's assertion [in the April 12, 2003 letter] that low dosage development was Fein's intellectual property." (*Id.* at 28.) This "assertion" was made as part of an explicit request for information about Ferring's Great Britain application. Barclay gave Speranza the information that Dr. Fein needed in order to assert priority.

Moreover, as Judge Sweet recognized, Ferring itself filed PCT '036 on September 20, 2002, in which it claimed priority to GB '397 and listed Dr. Fein among the inventors on that patent. (Equitable Estoppel Opinion ¶¶ 4–5.) Ferring cannot now plausibly claim that Dr. Fein sought to mislead the PTO by referring back to GB '397 when Ferring itself listed Dr. Fein as an inventor of GB '397.

Taken together, the Speranza-Barclay correspondence, Ferring's own PCT application, and Judge Sweet's broader conclusion that Dr. Fein reasonably believed that Ferring did not dispute his inventorship are "inconsistent with [the] knowledge of illegality" that is needed to sustain an inequitable conduct claim under Federal Circuit law and Rule 9(b). *See Exergen*, 575 F.3d at 1329 n.5 (internal citation omitted). No trier of fact could draw the factual inference necessary to a finding of scienter.

3. Example 8

Ferring alleges that Dr. Fein misled the PTO by including "Example 8" in the Patents in Suit. (Am. Compl. ¶¶ 144–46.) Example 8 describes a clinical study designed to evaluate the "antidiuretic effect of three low doses of desmopressin administered via intravenous infusion for 2 hours in over-hydrated, healthy, non-smoking male and female volunteers." (*Id.* Ex. C. at col. 20:39-42.) According to Ferring, Dr. Fein knew that there was an inventorship dispute over

Example 8, and nevertheless withheld that information from the PTO because it was crucial to the patentability of the Patents in Suit. (*Id.* ¶ 146.)

Once again, this allegation is directly at odds with Judge Sweet's findings concerning the Speranza-Barclay correspondence.

As noted (both above and in the Equitable Estoppel Opinion), Speranza sent a letter to Barclay on December 14, 2004 (to which Ferring never responded) further addressing Barclay's concerns about Dr. Fein's patent application. (*See* Equitable Estoppel Opinion ¶ 57.) Speranza's letter is remarkably illuminating. He wrote:

> Given your apparent concern with the content of Dr. Fein's published applications, we note in the interests of completeness that Dr. Fein filed a "continuation-in-part" U.S. patent application . . . . It is possible that you already know about this application, but in any event we have attached a copy of this published application for your convenience. *You will note that this published U.S. application, like the published PCT application, to which your letter related, repeats data as was set forth in the original Ferring UK application* [GB '397]. *For the reasons given in our earlier letter of this date, the inclusion of that data by Dr. Fein was in all respects proper* . . . .
>
> You will also note that Dr. Fein's published U.S. application contains data beyond that included in the original Ferring UK application. *See in particular "Example 8"* and "Figures 1–9" *of the published application. We trust that you will be able to quickly determine for yourself that the new data did not emanate from Ferring.* In any event, we can assure you that the new data in the application came from an independent clinical evaluation commissioned by Dr. Fein and conducted at his own expense.

(Dkt. No. 143 Ex. B AGN_FER000002786–87) (emphases added).)

Because Ferring failed to respond to this letter, or to suggest that anything in it was incorrect, for seven years, Judge Sweet concluded that Dr. Fein reasonably believed that Ferring did not dispute the subject matter of the Patents in Suit. (Equitable Estoppel Opinion at 15, 30, 34.)

As Speranza's December 14, 2004 letter illustrates, the subject matter of the Patents in Suit encompassed, among other things, Example 8. Speranza specifically directed Barclay's attention to Example 8, and invited her to "determine for [her]self [whether] the new data []

emanate[d] from Ferring." (*Id.*) But Barclay (and Ferring) elected not to, leading Judge Sweet to conclude that Fein reasonably believed that Ferring did not object to his patent application. In the face of that conclusion, the Court cannot now infer that Dr. Fein *fraudulently* concealed from the PTO that Example 8 was subject to an ownership dispute.

Finally, Ferring argues that, even accounting for the Equitable Estoppel Opinion, there are disputed facts that render its inequitable conduct claim plausible, because Judge Sweet—in granting Ferring's motion for summary judgment dismissing the defendants' counterclaims for a correction of inventorship in the 2012 Action—found that Dr. Fein was not the sole inventor on a *different* set of Ferring patents, Patent Nos. 7,560,429 and 7,947,654 (the "'429 and '654 Patents"). (Dkt. No. 13 Ex. 12; *see also* Dkt No. 12 Civ. 2650 Dkt. No. 212 (hereinafter referred to as the "2012 Summary Judgment Opinion").) Ferring argues that 2012 Summary Judgment Opinion is "instructive" because Dr. Fein's alleged inventive contributions to the '429 and '654 Patents and the Patents in Suit here (the '203 and '321 Patents) are the same. This, they suggest, means that Dr. Fein knowingly misled the PTO about inventorship of the '203 and '321 Patents. (Ferring's First Opp. at 8.)

The 2012 Summary Judgment Opinion has no bearing on the present motions. When it sought to prevent this case from being transferred to Judge Sweet, Ferring previously represented to Judge Hellerstein that the technologies at issue in the two sets of patents are different. (*See* Dkt. No. 63.) The Patents in Suit are "broadly directed to the clinical properties of drug products, including the levels of active ingredients in patients' bloodstreams, and are not limited to particular dosage forms." (*Id.* at 1.) By comparison, the '429 and '654 patents are "formulation patents, directed to specific tablet formulations." (*Id.*) The issue contemplated by the 2012 Summary Judgment Opinion, therefore, was whether Dr. Fein was a sole inventor on

claims directed to specific tablet formulations—an issue entirely different from the one encompassed by Ferring's present claim.

Defendants' motion to dismiss Count V of the Amended Complaint is granted.

b. Defendants' Motion for Judgment on the Pleadings to Dismiss Allegations of Improper Inventorship is Granted

Count I of the Amended Complaint in this action asks the Court to declare the Patents in Suit invalid under 35 U.S.C. § 102, in part because "Dr. Fein did not himself invent the subject matter claimed in the Patents in Suit." (Am. Compl. ¶ 116.) Counts I and II of Ferring's first amended complaint in the 2012 Action sought correction of inventorship, pursuant to 35 U.S.C. § 256, of the '203 and '321 Patents on the same basis—that "Fein did not invent any subject matter covered by" those patents. (12 Civ. 2650 Dkt. No. 73 ¶¶ 112 ('203 Patent), 127 ('321 Patent).) In other words, while the claims may be different, the issues presented by the two are identical, *viz*, whether Fein, the named inventor, is the inventor of the '203 and '321 Patents. It follows, Defendants argue, that Ferring is collaterally estopped from litigating that issue here, since Judge Sweet determined that Ferring was equitably estopped from contesting the same underlying issue—Dr. Fein's inventorship—in the context of a different claim.

The doctrine of collateral estoppel, which is also known as issue preclusion, bars a party from re-litigating in a second proceeding a factual or legal or issue that has already been decided against him in a prior proceeding. *Poindexter v. Cash Money Records*, No. 13-cv-1155 (RWS), 2014 WL 818955, at *3 (S.D.N.Y. Mar. 3, 2014) (citing *Allen v. McCurry*, 449 U.S. 90, 94 (1980)). "Because the application of collateral estoppel is not a matter within the exclusive jurisdiction of [the Federal Circuit], . . . the law of the circuit in which the district court sits" controls the questions of whether collateral estoppel applies. *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1345 (Fed. Cir. 2002).

"Even though a plaintiff's factual allegations must be accepted as true and all reasonable inferences drawn in the plaintiff's favor on a motion to dismiss, collateral estoppel will nonetheless bar a plaintiff's claim when the plaintiff's 'factual allegations have been decided otherwise in previous litigation.'" *Poindexter*, 2014 WL 818955, at *3 (quoting *Jacobs v. Law Offices of Leonard N. Flamm*, No. 04 Civ. 7607, 2005 WL 1844642, at *3 (S.D.N.Y. July 29, 2005)). Collateral estoppel attaches where (*i*) an identical issue was raised in a previous proceeding against the party; (*ii*) the issue was actually litigated and decided in the previous proceeding; (*iii*) the party had a full and fair opportunity to litigate the issue; and (*iv*) resolution of the issue was necessary to support a valid and final judgment on the merits. *Flood v. Just Energy Mktg. Corp.*, 904 F.3d 219, 236 (2d Cir. 2018) (citations omitted). Courts have broad discretion to determine whether collateral estoppel applies. *See Marcel Fashions Grp., Inc. v. Lucky Brand Dungarees, Inc.*, 898 F.3d 232, 241 (2d Cir. 2018) (citing *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 331 (1979)).

Before applying the four collateral estoppel factors, the Court must grapple with a definitional question: What is the "issue" that Defendants assert that Ferring is collaterally estopped from challenging in this action?

Ferring characterizes the "issue" as Dr. Fein's inventive contributions to the Patents in Suit—an issue, Ferring argues, that Judge Sweet never "substantive[ly] examin[ed]" because "he terminated the proceeding" on equitable estoppel grounds. (Ferring's Opp. to Def.'s Second Mot. for J. on the Pleadings, dated Oct. 5, 2018, ("Ferring's Second Opp."), at 2, Dkt. No. 241 (emphasis in original).) Having framed the issue in this manner, Ferring has made what might appear at first blush a compelling argument—because Judge Sweet, indeed, did not assess the

degree of Dr. Fein's inventive contributions to the '203 and '321 Patents in the Equitable Estoppel Opinion.

But Ferring's characterization is a classic straw man. Defendants' motion is not based upon whether Judge Sweet reached the merits of the parties' inventorship dispute; it is based upon whether Ferring can even dispute inventorship now—in the context of a different claim and in a different action—in light of Judge Sweet's earlier determination that Ferring delayed unduly in challenging Dr. Fein's inventorship status.[6]

Having now defined the "issue" to be considered for preclusion, the Court can proceed to applying the four collateral estoppel factors.

The issue of Ferring's undue delay in challenging Dr. Fein's inventorship of the '203 and '321 Patents was raised in the 2012 Action. (*See* Equitable Estoppel Opinion ¶ 58). That issue was "actually litigated and decided" in the 2012 Action. (*See id.* at 21–37.) Ferring had a full and fair opportunity to litigate the issue; indeed, Judge Sweet even granted Ferring's motion for an extension of time to respond to its adversaries' briefing on equitable estoppel. (*See* 12 Civ. 2650 Dkt. No. 143.) And the issue of Ferring's undue delay in challenging inventorship of the '203 and '321 Patents was necessary (indeed, crucial) to Judge Sweet's ultimate decision to grant Defendants' motion for summary judgment on Ferring's correction of inventorship claims (*see generally* Equitable Estoppel Opinion). Ferring does not (and, indeed, cannot reasonably) dispute any of these conclusions.

The motion nonetheless raises three significant issues.

The first is that different statutory bases underlie Ferring's earlier and present inventorship claims. In the 2012 Action, Ferring asserted claims under 35 U.S.C § 256, seeking

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[6] In fairness to Ferring, Defendants' opening brief also confused the "issue" for which it sought preclusion.

to correct inventorship of the '203 and '321 Patents. Here, Ferring seeks a declaration that the '203 and '321 Patents are invalid under 35 U.S.C. § 102. Patent invalidity is a defense to patent infringement; as Ferring argues, it could not have raised that defense "until the approval of its NOCDURNA® product was imminent." (Ferring's Second Opp. at 3.) Ferring argues that precluding it from asserting that defense now (which depends, in part, on challenging Dr. Fein's inventorship) would be manifestly unfair, because this is the first opportunity that Ferring has had to raise the defense.

This argument confuses claim preclusion and issue preclusion.[7] Collateral estoppel (*i.e.*, issue preclusion) prevents a party from re-litigating certain factual issues, even in the context of different legal claims. "Under collateral estoppel, once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits *based on a different cause of action involving a party to the prior litigation.*" *Montana v. United States*, 440 U.S. 147, 153 (1979) (emphasis added); *see also Wyly v. Weiss*, 697 F.3d 131, 140 (2d Cir. 2012) (issue preclusion "bars successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment, *even if the issue recurs in the context of a different claim.*") (emphasis added).

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[7] This confusion is somewhat understandable. Preclusion law is one of the most oft-confused doctrines in civil procedure. *See, e.g.*, *Migra v. Warren City Sch. District Bd. of Educ.*, 465 U.S. 75, 77 n.1 (1984) ("The preclusive effects of former adjudication are discussed in varying and, at times, seemingly conflicting terminology."). Litigants often use terms like "res judicata" and "collateral estoppel" interchangeably; even courts confuse the terms on occasion. *See, e.g.*, *Int'l Air Response v. United States*, 324 F.3d 1376, 1378 (Fed. Cir. 2003) (parties petitioned court to clarify its use of terms when court used "res judicata" but applied collateral estoppel doctrine). Some authorities describe res judicata as encompassing both issue and claim preclusion. *See, e.g.*, *Leal v. Krajeweski*, 803 F.2d 332, 334 (7th Cir. 1986); *accord Elliott v. Univ. of Tenn.*, 766 F.2d 982, 986 n.1 (6th Cir. 1985), *aff'd in part, rev'd in part*, 478 U.S. 788 (1986) ("Throughout this opinion, we will intend 'res judicata' and 'rules of preclusion' to refer to principles of both issue and claim preclusion."); *cf. Weaver Corp. v. Kidde, Inc.*, 701 F. Supp. 61, 63 (S.D.N.Y. 1988) ("One difficulty is that courts use 'res judicata' for two different concepts. Some use it to mean claim preclusion. Others employ res judicata in a general sense, to encompass both claim and issue preclusion."). In this Court's opinion, *res judicata* refers to claim preclusion, and collateral estoppel refers to issue preclusion.

In thinking about Defendants' motion, the Court is guided by the policies underlying the doctrine of collateral estoppel. "Collateral estoppel saves parties and the courts from the waste and burden of relitigating stale issues, and, by discouraging inconsistent results, forwards public policy favoring the establishment of certainty in legal relations." *United States v. Alcan Aluminum Corp.*, 990 F.2d 711, 719 (2d Cir. 1993) (citation omitted); *see also Envtl. Def. v. EPA*, 369 F.3d 193, 202 (2d Cir. 2004) ("The doctrine serves to 'relieve parties of the cost and vexation of multiple lawsuits, conserve judicial resources, and, by preventing inconsistent decisions, encourage reliance on adjudication.'" (quoting *Allen*, 449 U.S. at 94)). Permitting Ferring to challenge Dr. Fein's inventorship anew, albeit in the context of a different claim, would undermine every one of the rationales underlying collateral estoppel. By contrast, Ferring will not be substantially prejudiced if the Court were to grant Defendants' motion, because it can still assert (and, indeed, it has asserted) other bases for invalidating the Patents in Suit—none of which is affected by the issue of inventorship. Collateral estoppel simply precludes Ferring from making one of its several arguments in support of invalidity.

The second issue relates to the consequences, if any, of Judge Sweet's recent *Markman* decision in this action. Ferring argues that the *Markman* decision precludes the Court from applying the doctrine of collateral estoppel, because it establishes that the Patents in Suit "contain claims 'different in scope' compared to the alleged 'low dosage' invention that Dr. Fein purportedly relied upon (*i.e.*, as defined in the Speranza[-Barclay] correspondence)[.]" (Ferring's Supp. Mem. at 6.) This is the same argument it raised earlier in opposing Defendants' motion directed at Count V—namely, that the "invention" that was contemplated by Speranza and Barclay when they corresponded was limited to a "low dosage" of desmopressin, not the broader inventions that are the subject of the Patents in Suit.

For the reasons discussed earlier, the Court rejects Ferring's interpretation of the Equitable Estoppel Opinion, as well as its suggestion that the *Markman* decision precludes this Court from applying the doctrine of collateral estoppel. *Supra* at 16–18. Both the '203 and '321 Patent claims and the claims in the patent applications that Speranza sent to Barclay on December 14, 2004 included the inventive features of establishing low plasma/serum levels and contemplated various routes of desmopressin administration. The Equitable Estoppel Opinion was not limited to a "low dose" invention, so Judge Sweet's *Markman* decision does not foreclose Defendants' present motion. (Ferring's Supp. Mem. at 4–5.)

The final and most difficult issue is whether the Equitable Estoppel Opinion constitutes a "final" judgment for collateral estoppel purposes. *See Flood*, 904 F.3d at 236. (collateral estoppel requires both "valid" and "final" judgment on the merits).

Neither party considered this particular issue in the first three rounds of briefing they exchanged; Ferring finally raised this argument to the Court in a letter, dated May 14, 2019, in which it advised this Court that it had filed a motion to vacate the Equitable Estoppel Opinion, pursuant to Fed. R. Civ. P. 60(b), in the 2012 Action. It argues that this should cause me to find that the Equitable Estoppel Opinion lacks preclusive effect. (Dkt. No. 497; *see also* 12 Civ. 2560 Dkt. No. 373 (Ferring's motion to vacate Collateral Estoppel Opinion).) At the Court's direction, the parties then filed a fourth round of briefs—both of which were heavy on argument but thin on case law analysis.

As the parties well know, the 2012 Action is ongoing; a bench trial in that case—previously interrupted and postponed, for reasons not relevant here—is scheduled to recommence in July 2019. This means that Ferring has not had an opportunity to appeal the

Equitable Estoppel Opinion. That fact arguably counsels against preclusion, but it is not dispositive of the issue.

"Finality" within the meaning of collateral estoppel is a more flexible concept than it is in other contexts, including under 28 U.S.C. § 1291 and Fed. R. Civ. P. 54. Critically, collateral estoppel in not limited to opinions that "end[] the litigation and leave[] nothing for the court to do but execute the judgment.'" *Lummus Co. v. Commonwealth Oil Ref. Co.*, 297 F.2d 80, 89 (2d Cir. 1961), *cert. denied*, 368 U.S. 986 (1962) (quoting *atlin v. United States*, 324 U.S. 229, 233 (1945)). Rather, in this Circuit, whether a ruling is sufficiently "final" for preclusion purposes turns on "such factors as the nature of the decision (*i.e.*, that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review." *Id.*

Before applying the *Lummus* factors to the case at bar, the Court must dispose of two threshold arguments raised by Ferring.

First, Ferring asserts that Defendants are attempting to use collateral estoppel in an "offensive" posture, and, therefore, they must demonstrate that applying collateral estoppel to this case would be "fair," in addition to also satisfying the three *Lummus* factors. (Ferring's Supp. Mem. of Law. on Finality ("Ferring's Supp. Br.") at 1, dated May 23, 2019, Dkt. No. 504 (citing *Flood*, 904 F.3d at 236).)

But Ferring is incorrect that Defendants are using estoppel offensively. "The doctrine of offensive collateral estoppel allows a plaintiff to preclude a defendant from relitigating an issue that has been previously decided against the same defendant." *Flood*, 904 F.3d at 236. Here, Serenity, Reprise, and Avadel—the Defendants—are using the doctrine defensively, in response to Ferring's claims against them.[8]

[8] Ferring's failure to distinguish between offensive and defensive collateral estoppel renders its reliance on *Flood*—an offensive collateral estoppel case where the plaintiffs sought to "cherry pick a decision in their favor to

However, the concept of "fairness" is very much central to the Court's thinking on this issue—as will be seen below.

Second, Ferring cites *Gelb v. Royal Globe Ins. Co.*, 798 F.2d 38, 44 (2d Cir. 1986), for the proposition that, "although *failure* to appeal does not prevent preclusion, [the] *inability* to obtain appellate review, or the lack of such review once an appeal is taken, does prevent preclusion." (Ferring's Supp. Br. at 1 (emphases added for clarity).) This selective citation to dictum in *Gelb*—with the suggestion that the lack of opportunity to appeal a decision precludes the application of collateral estoppel in this Circuit—is unavailing. *Gelb*'s reference to an "inability to obtain appellate review" refers, not to cases that are temporarily unreviewable because proceedings are ongoing, but rather to decisions that are, by law, unreviewable by their very nature. *See Medisys Health Network, Inc. v. Local 348-S United Food & Commercial Workers, AFL-CIO, CLC*, 337 F.3d 119, 124 (2d Cir. 2003) (decisions made by district court attendant to remand order likely have no preclusive effect, because such orders are unreviewable as a matter of law, "whether erroneous or not") (citing *Gelb*, 798 F.2d at 44). *Accord United States v. Walker*, 239 F. Supp. 3d 738, 741 (S.D.N.Y. 2017) (interpreting the passage above from *Gelb* as dictum).

Ferring conveniently overlooks the numerous Second Circuit cases—decided both before and after *Gelb*—that have reaffirmed *Lummus*'s fundamental holding that an interlocutory decision can be given preclusive effect.

In *Zdanok v. Glidden Co.*, 327 F.2d 944 (2d Cir. 1964), the court reiterated, "collateral estoppel does not require a judgment which ends the litigations and leaves nothing for the court to do but execute a judgment, but includes many dispositions which, though not final in that

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invoke collateral estoppel, while at the same time overlooking a decision that [held] against them," 904 F.3d at 237—particularly unpersuasive.

sense, have nevertheless been fully litigated." (quoting *Lummus*, 297 F.2d at 89 & *Catlin*, 324 U.S. at 233). In *Kurlan v. Comm. of Internal Revenue*, 343 F.2d 625, 628 n.1 (2d Cir. 1965), the court again stated, "[G]eneral expressions that only final judgments can ever have collateral estoppel effect are considerably overstated." Post-*Gelb*, in *Metromedia Co. v. Fugazy*, 983 F.2d 350 (2d Cir. 1992), the court—after citing to *Lummus* and *Zdanok* with approval—noted that "recent decent have relaxed traditional views of the finality requirement[.]" *Id.* at 366 (quoting 18 Wright & Miller § 4434 ("Recent decisions have relaxed traditional views of the finality requirement by applying issue preclusion to matters resolved by preliminary rulings or to determinations of liability that have not yet been completed by an award of damages or other relief.")).

Finally, the *Restatement (Second) of Judgments*—which numerous courts in this Circuit (including the Second Circuit itself) have embraced, *e.g.*, *EDP Med. Computer Sys., Inc. v. United States*, 480 F.3d 621, 626 (2d Cir. 2007)—states that a judgment should be given collateral estoppel effect where it is "firm and stable," *i.e.*, the "last word" of the rendering court on a particular issue, even if it is not yet appealable. *Restatement (Second) of Judgments* § 13, cmt. a.

Having disposed of Ferring's threshold arguments, taking into account the Second Circuit and Restatement's flexible conception of "finality," and applying the *Lummus* factors to the matter at hand, the Court concludes that Judge Sweet's Equitable Estoppel Opinion is a "final" order for collateral estoppel purposes. Even though it is not yet appealable, that decision rests on sturdy grounds, as it was both well-reasoned and the product of a full and fair opportunity for the parties to be heard.

As to the former, Judge Sweet's 37-page Opinion clearly articulated the pertinent facts underlying his decision and grappled with challenging questions of law. (*See, e.g.*, Equitable Estoppel Opinion at 24 (identifying competing authorities on both sides of the "close question" of "[w]hether misleading conduct may precede an actual patent" for equitable estoppel to apply).) Indeed, the Opinion constitutes a textbook district court opinion—one that identifies and applies binding authority, derives legal principles from persuasive authority, and applies case law to the particulars of the case.

As to the latter, both parties submitted extensive briefing on Defendants' summary judgment motion. And Ferring—having applied for and received an extension—did so with extra time. (*See* 12 Civ. 2650 Dkt. No. 143.) Under these circumstances, Ferring cannot (and, indeed, does not) contend that it was deprived of an opportunity to be heard on the issue of equitable estoppel.

The Court's conclusion is supported by ample case law.

Particularly compelling is Judge Rakoff's recent decision in *United States v. Walker*, 239 F. Supp. 3d 738 (2017). In that case, the defendant sought to suppress certain evidence obtained from a search of his bedroom. In a different proceeding under a separate indictment but involving the same search of his bedroom, a different judge, Judge Abrams, concluded that the defendant had consented to a police search. *Id.* at 739. Despite the fact that the case before Judge Abrams had not concluded and, thus, her earlier decision was not yet appealable, Judge Rakoff ruled that her opinion was "final" for collateral estoppel purposes, thereby preventing the defendant from re-litigating the issue of whether the police search was voluntary. *Id.* at 740. Had the court yielded to the risk that Judge Abrams' decision might one day be overturned on appeal, it would, in effect, have "render[ed] *Lummus*'s long-established rule of practical finality

a dead letter," because it "would [have] amount[ed] to a bright-line requirement that an order must always be subject to appellate review before it has any preclusive effect." *Id.* at 742. "[T]he availability of appellate review is merely one factor to consider[.]" *Id.* at 741.

In concluding that collateral estoppel applied, Judge Rakoff analogized the case to *TM Patents, L.P. v. Int'l Bus. Machines Corp.*, 72 F. Supp. 2d 370, 374 (S.D.N.Y.)—another case that resonates here. In *TM Patents*, I gave preclusive effect to a prior federal court's construction of a patent—even though the parties in that case reached a settlement following the *Markman* decision, so the decision was never appealed. *See* 72 F. Supp. at 376–77. Applying the *Lummus* factors, I concluded that the opinion was final, because the district court had held a two-day hearing, "issued a very thorough ruling" that "dispos[ed] of all disputed issues," and relied on that ruling to give preliminary jury instructions. *Id.* at 377. As to claim construction, "[n]othing more remained to be adjudicated[,]" and so "the results of the *Markman* hearing in the [earlier action] were sufficiently 'final' to permit application of collateral estoppel—even though the matter to which they were necessary was never reduced to a final judgment after verdict." *Id.*

In addition to *Walker* and *TM Patents*, I have located a few decisions in this Circuit in which it was held that a partial grant of summary judgment in an earlier proceeding—the very type of opinion at issue here—constitutes a "final" order for collateral estoppel purposes.

For example, in *United States v. McGann*, 951 F. Supp. 372 (E.D.N.Y. 1997), the court granted partial summary judgment in an earlier proceeding on the basis that the government's civil claim for breach of fiduciary duty was barred under the statute of limitations. *Id.* at 379–80. After unsuccessfully seeking leave to amend the complaint in the first action, the government filed a second action alleging breach of fiduciary duty against the same defendant, but only as to a later time period. On a motion to dismiss, the defendant argued that the court should give

collateral estoppel effect to the issues litigated in the earlier summary judgment opinion, even though the earlier case was ongoing as to other claims. *Id.* at 380.[9]

The court agreed. Noting the "decisive resonance between the Restatement" approach to "finality" and *Lummus*, *id.* at 381, the court concluded that the earlier partial grant of summary judgment was final despite the absence of (and, indeed, an ability to take) an appeal, because "the discrete issue of breach of fiduciary duty ha[d] reached such a stage that th[e] court s[aw] no good reason for permitting it to be litigated yet again." *Id.* at 382. In so holding, the court embraced the reasoning of *Sherman v. Jacobson,* 247 F. Supp. 261 (S.D.N.Y. 1965), which emphasized—like *Lummus*—that finality is a case-specific inquiry, with a view towards "'prevent[ing] [the] enfeebling of judicial administration.'" *Id.* (quoting *Sherman*, 247 F. Supp. at 268). "Finality" should not be construed too narrowly, the court warned, or else it will "'allow a litigant to bring an endless number of lawsuits.'" *Id.* (quoting *Sherman*, 247 F. Supp. at 268).

Also instructive is *Georgakis v. E. Air Lines, Inc.*, 512 F. Supp. 330 (E.D.N.Y. 1981). In that case, the plaintiff, who was injured in an airplane crash while traveling with the defendant-airline company, sought summary judgment on the airline's affirmative defense that the case was covered by the Warsaw Convention, which would have limited the plaintiff's damages to $75,000. In a prior case arising out of the same crash brought by a different passenger, the court had granted summary judgment against the airline, dismissing the Warsaw Convention defense. The passenger in *Georgakis*, therefore, invoked collateral estoppel. *Id.* at 333.

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[9] While the opinion does not clearly make this point, the docket sheet from the earlier proceeding establishes that the initial case was still ongoing after the second action was dismissed; thus, the Government could not have appealed the court's partial grant of summary judgment prior to dismissal of the second action. On a motion under Fed. R. Civ. P. 12(b), the Court can take judicial notice of filings in another action. *See Global Network Commc'ns, Inc. v. City of N.Y.*, 458 F.3d 150, 157 (2d Cir. 2006) ("A court may take judicial notice of a document filed in another court not for the truth of the matters asserted in the other litigation but rather to establish the fact of such litigation and related filings.").

Rejecting the airline's argument that the interlocutory nature of the earlier decision precluded application of collateral estoppel, the court noted that collateral estoppel "does not require a judgment 'which ends the litigation . . . and leaves nothing for the court to do but execute the judgment,' . . . but includes many dispositions which, although not final in that sense, have nevertheless been fully litigated." *Id.* at 334 (quoting *Zdanok*, 327 F.2d at 955). "Under the authority of *Zdanok* and its progeny, this Court concludes that the interlocutory setting of the disposition of the [Warsaw convention issue] in [the earlier proceeding] does not prevent that disposition from collaterally estopping [the defendant from litigating the identical issue on identical facts in the instant case." *Id.* "[T]his Court 'sees no really good reason for permitting it to be litigated again.'" *Id.* (quoting *Lummus*, 297 F.2d at 89).

Other courts in this Circuit have similarly concluded that a partial grant of summary judgment may be "final" for collateral estoppel purposes. *See USM, Inc. v. Barretta Enterprises, LLC*, No. 3:15CV1537 (DJS), 2016 WL 5339719, at *4 (D. Conn. Sept. 21, 2016); *Dep't of Justice v. Hudson*, No. 1:06-CV-763, 2007 WL 2461783, at *4 (N.D.N.Y. Aug. 24, 2007), *opinion vacated in part on reh'g sub nom on other grounds, U.S. Dep't of Justice, Tax Div. v. Hudson*, No. 1:06-CV-763 FJS, 2009 WL 7172812 (N.D.N.Y. July 8, 2009); *see also Creed Taylor, Inc. v. CBS, Inc.*, 718 F. Supp. 1171 (S.D.N.Y. 1989) (rejecting as "lack[ing] merit" plaintiff's argument that a partial grant of summary judgment from earlier proceeding was not final for collateral estoppel purposes, but declining to apply preclusion because issue previously decided was not resolved on the merits).

Indeed, the Court has located only one case in this Circuit where an unappealable partial grant of summary judgment in an earlier proceeding was not deemed "final" for collateral estoppel purposes. This case, however, is not persuasive.

In *Paone v. Broadcom Corp.*, No. 15 Civ. 0596 (BMC)(GRB), 2015 WL 4988279 (E.D.N.Y. Aug. 19, 2015), the defendant, Broadcom Corp. ("Broadcom"), filed a motion to dismiss on the basis that the plaintiff, an individual named Luciano Paone, was collaterally estopped from asserting certain theories of patent infringement against the company because those theories were rejected and dismissed on summary judgment in an earlier case—albeit one involving a different defendant (Microsoft)—concerning the same patent and technology that was at issue in *Paone*. Critically, the case against Microsoft ultimately settled, so the earlier summary judgment opinion was not appealable. *Id.* at *1.

The court rejected Broadcom's argument that collateral estoppel should apply, because it concluded that the earlier partial grant of summary judgment was not "final." *Id.* at *10–12. Declaring that *Lummus*, its progeny, and the Restatement approach "only go[] so far," the court noted that "some courts have been strict in requiring that an order be appealable before it is entitled to preclusive effect." *Id.* at *11 (citing *Avondale Shipyards, Inc. v. Insured Lloyds*, 786 F.2d 1265, 1271 (5th Cir. 1986) (citing, *inter alia*, *Acha v. Beame*, 570 F.2d 57 (2d Cir. 1978))).[10]

Central to the court's reasoning was *Kay-R Elec. Corp. v. Stone & Webster Const. Co.*, 23 F.3d 55 (2d Cir. 1994). In *Kay-R Electric*, the Second Circuit (applying *Lummus* and the Restatement) held that an order denying a motion for summary judgment was not entitled to preclusive effect, principally because it was not subject to review. 23 F.3d at 59. According the

[10] *Acha* concerned whether a lower court had correctly certified an order for appeal under Fed. R. Civ. P. 54(b). The Second Circuit panel concluded that the lower court erred in certifying the case. 570 F.3d 62–63. Although estoppel played a tangential role in the decision—the appellant argued that the district court did not err in certifying the appeal, and therefore the case was final for *res judicata* (not collateral estoppel) purposes—*Acha* did not actually define the contours of "finality" within the meaning of collateral estoppel or *res judicata*. It concerned, instead, the concept of "finality" within the meaning of Rule 54.

court in *Paone*, the logic of that case applied with equal force in the scenario before it, where there had been a *grant* of summary judgment in the earlier proceeding:

> It seems to me that this reasoning applies with equal force to a partial grant of summary judgment that forms the basis for a settlement. I am cognizant of the concern expressed by some courts that by declining to give preclusive effect to pre-settlement summary judgment, a strategic escape is created for a losing party on an interlocutory motion, especially if (as here) he is a repeat player.
>
> Nevertheless, such considerations are a legitimate part of the settlement calculus, and parties should be free to choose that avenue for resolving their disputes without binding themselves to interlocutory determinations that they had no opportunity to challenge.

Id. (internal citations omitted).

The court's opinion also relied upon fairness and efficiency principles. It reasoned that Broadcom would not be prejudiced by the denial of its motion, because the court would afford substantial deference to the factual findings of the judge who presided over the earlier Paone-Microsoft dispute, and only allow Paone's case against Broadcom to proceed if he could demonstrate that the earlier judge erred in some fashion. *Id.* at *12.

Despite certain factual similarities—both cases are patent infringement cases where the defendant seeks to prevent the plaintiff from re-litigating an issue previously decided against it—*Paone* is not persuasive.

For one thing, the notion that courts outside this Circuit have treated appealability as the *sine quo non* of collateral estoppel is, in view of *Lummus* and its progeny, not persuasive to this Court, which must apply Second Circuit law.

For another, the Court rejects the suggestion that *Kay-R Electric* extends to the circumstances presented in here. It goes without saying that the denial and grant of summary judgment mean two very different things. Where a judge denies summary judgment, she is impliedly withholding a decision on a given issue because there is a genuine issue of material

fact. In contrast, a grant of summary judgment reflects that there is no genuine dispute of material fact on any issue. One can readily imagine why the former does not have any preclusive effect. But it hardly follows that, since the former is not final, the latter is not either. If there is no genuine issue of fact, the facts necessary to the decision in granting summary judgment are *ipso facto* final—and, therefore, *do* have preclusive effect.

Finally, the circumstances underlying this case and *Paone* are markedly different. Where, as here, the same set of parties have been embroiled in seven years of litigation in this District (which is to say nothing of the legal battles the parties are waging in other forums), fairness and judicial efficiency are not served by disturbing what strikes me as a manifestly "final" decision on the issue of inventorship. This is especially so in light of the fact that the Court has under taken the rigorous task of reviewing *de novo* the Equitable Estoppel Opinion and has independently arrived at the same legal conclusions as Judge Sweet. *Cf. Walker*, 239 F. Supp. 3d at 742 (noting that Court undertook the same *de novo* review, but stating that, "if other courts find this Opinion persuasive, such duplication of effort will not be required in the future").

For all of these reasons, the Court concludes that the Equitable Estoppel Opinion is "final" for collateral estoppel purposes.

Therefore, Ferring is collaterally estopped from challenging Dr. Fein's inventorship of the Patents in Suit. Its allegations to that effect in support of its patent invalidity claim (Count I) are dismissed.

III. Setting a Trial Schedule

The parties informed the Court at the April 22, 2019 status conference that Defendants' outstanding Rule 12(c) motions represented the biggest hurdles in terms of their ability to conclude discovery.

Now that we have cleared those hurdles, it is time to set a trial schedule.

This case will be tried beginning January 6, 2019. That should give the parties time to deal with the trial before Judge Castel and finish expert discovery in this case.

It is my understanding that this will be a bench trial. Therefore, the parties should adhere to the following schedule:

Stipulated facts, proposed findings of fact and conclusions of law, a copy of all exhibits (limited to 100 documents per side), and written objections to the admissibility of any exhibits must be filed with the Court no later than November 15, 2019. Do not attach pleadings as exhibits, unless you are offering discrete statements from pleadings as party admissions—in which case, extract them and create an exhibit.

In limine motions, if any, must be filed with the court on or before November 29, 2019. Each *in limine* motion must be a separate motion—no omnibus motions—and must be supported by a brief of no more than five double spaced pages. Responses to *in limine* motions must be filed with the court on or before December 9, 2019. Responses must consist of a brief of no more than five double spaced pages. The Court does not accept replies on *in limine* motions. In a bench trial, the Court rarely excludes evidence.

If anyone plans to make a *Daubert* motion, it must be filed no later than October 18, 2019, with any response due November 1, 2019. Motions are limited to briefs of 10 double spaced pages. The Court does not accept replies on *Daubert* motions. If your motion really

boils down to, "Their expert does not agree with our expert, so strike their expert's testimony," please do not bother making a *Daubert* motion.

A final pre-trial conference will be held on December 19, 2019 at 10 AM.

CONCLUSION

Based upon the foregoing, Defendants' motions are granted. Count V of the Amended Complaint is dismissed. Ferring's allegations of improper inventorship, which it has asserted in support of Count I, are hereby dismissed.

The Clerk of Court is respectfully directed to close the open motions at Dkt. Nos. 148 and 206.

It is so ordered.

Dated: June 12, 2019

Chief Judge

BY ECF TO ALL COUNSEL